

## Checklist of Items for Reporting Trials of Nonpharmacologic Treatments\*

| Section                    | Item | Standard CONSORT Description  | Extension for Nonpharmacologic Trials   | Reported on Page No.             |
|----------------------------|------|---|---|----------------------------------|
| <b>Title and abstract†</b> | 1    | How participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”)  | In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status  | Page 1                           |
| <b>Introduction</b>        |      |   |   |                                  |
| Background                 | 2    | Scientific background and explanation of rationale  |   | Page 5                           |
| <b>Methods</b>             |      |   |   |                                  |
| Participants†              | 3    | Eligibility criteria for participants and the settings and locations where the data were collected  | When applicable, eligibility criteria for centers and those performing the interventions  | Page 6 + eSupplement 1           |
| Interventions†             | 4    | Precise details of the interventions intended for each group and how and when they were actually administered   | Precise details of both the experimental treatment and comparator   | Page 6/7 and eSupplement 2 and 3 |
|                            | 4A   |   | Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants | Page 6/7 and eSupplement 2 and 3 |
|                            | 4B   |   | Details of how the interventions were standardized  | Page 6/7 and eSupplement 2 and 3 |
|                            | 4C   |   | Details of how adherence of care providers with the protocol was assessed or enhanced   | n.a.                             |
| Objectives                 | 5    | Specific objectives and hypotheses  |   | Page 5                           |
| Outcomes                   | 6    | Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors) |   | Page 7 and eSupplement 1         |

|                                    |          |   |  |          |
|------------------------------------|----------|---|--|----------|
| Sample size†                       | 7        | How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules   | When applicable, details of whether and how the clustering by care providers or centers was addressed  | Page 11  |
| Randomization–sequence generation† | 8        | Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)   | When applicable, how care providers were allocated to each trial group   | Page 8   |
| Allocation concealment             | 9        | Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned   |  | Page 8   |
| Implementation                     | 10       | Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups   |  | Page 8   |
| Blinding (masking)†                | 11A      | Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment   | Whether or not those administering co-interventions were blinded to group assignment   | Page 8   |
|                                    | 11B      |   | If blinded, method of blinding and description of the similarity of interventions†   | Page 8   |
| Statistical methods†               | 12       | Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses   | When applicable, details of whether and how the clustering by care providers or centers was addressed  | Page 8/9 |
| <b>Results</b>                     |          |   |  |          |
| Participant flow†                  | 13       | Flow of participants through each stage (a diagram is strongly recommended)---specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons | The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center | Figure 1 |
| Implementation of intervention†    | New item |   | Details of the experimental treatment and comparator as they were implemented  | n.a.     |
| Recruitment                        | 14       | Dates defining the periods of recruitment and follow-up   |  | Page 9   |

|                         |    |   |   |                   |
|-------------------------|----|---|---|-------------------|
| Baseline data†          | 15 | Baseline demographic and clinical characteristics of each group   | When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group                                     | Table 1           |
| Numbers analyzed        | 16 | Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (e.g., 10/20, not 50%) |   | Figure 1          |
| Outcomes and estimation | 17 | For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)   |   | Table 2           |
| Ancillary analyses      | 18 | Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory                                    |   | Page 10           |
| Adverse events          | 19 | All important adverse events or side effects in each intervention group   |   | Figure 1, Page 11 |
| <b>Discussion</b>       |    |   |   |                   |
| Interpretation†         | 20 | Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes                      | In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group            | Page 11-13        |
| Generalizability†       | 21 | Generalizability (external validity) of the trial findings  | Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial | Page 11-13        |
| Overall evidence        | 22 | General interpretation of the results in the context of current evidence  |   | Page 11-13        |

\*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.

†This item was modified in the 2007 revised version of the CONSORT checklist.